

Notice of Allowability

Application No.

09/687,951

Examiner

Chih-Min Kam

Applicant(s)

CLELAND ET AL.

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1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/1/07.
2. ☒ The allowed claim(s) is/are 20,22,23,25-29,31,33,34,36 and 40-43.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20070522</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>2/21/07;6/1/07</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

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DETAILED ACTION

Status of the Claims

1. Claims 20, 22-23, 25-29, 31, 33-34, 36 and 40-43 are pending.

Applicants' request for reconsideration filed on June 1, 2007 is acknowledged.

Applicants' response has been fully considered. Thus, claims 20, 22-23, 25-29, 31, 33-34, 36 and 40-43 are examined.

Information Disclosure Statement (IDS)

2. The references listed on the IDS filed June 1, 2007 (same as the IDS filed February 21, 2007) have been considered.

Withdrawn Claim Objections

3. The previous objection of claims 33 and 36 is withdrawn in view of applicants' response at pages 10-11 in the amendment filed June 1, 2007.

Withdrawn Claim Rejections - 35 USC § 103

4. The previous rejection of claims 20, 22, 23, 25-29, 31, 34 and 40-43 under 35 U.S.C. 103(a) as being unpatentable over Suzuki *et al.* (US Patent 6,197,326) in view of Igari *et al.* (US Patent 5,416,071), is withdrawn in view of applicants' response at pages 6-10 in the amendment filed June 1, 2007.

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Denise Kettelberger on August 14, 2007.

Examiner's Amendment to the Claims:

Claim 20 has been amended as follows:

20. (Currently amended) A method for administering a biologically active agent, the method comprising:

injecting to an animal a formulation comprising:

- (a) an injection vehicle comprising hyaluronic acid dissolved in a physiological buffer at a concentration of about 0.01 to about 3 percent weight per volume; and
- (b) particles comprising:
 - (i) a first component that is the biologically active agent; and
 - (ii) a second component that is a biocompatible polymeric matrix, wherein the concentration of the polymeric matrix is about 1 mg/mL to about 500 mg/mL of formulation.

The following is an **Examiner's Statement of Reasons for Allowance**: The following references appear to be related to the claimed invention. Suzuki *et al.* (US Patent 6,197,326) teach an intra-articular preparation for the treatment of arthropathy, which comprises microcapsules of a biocompatible, high molecular weight substance such as PLGA, homopolymer or copolymer of lactic acid, glycolic acid and caprolactone, and a drug such as cyclosporin; and the microcapsules can be administered in the form of injection by suspending it in a dispersion medium such as water, where a buffer, NaCl, hyaluronic acid, or chondroitin sulfate or salts thereof can be added. However, Suzuki *et al.* does not teach the concentration of hyaluronic acid is about 0.01 to about 3% (w/v) in a physiological buffer, and the concentration of a polymeric matrix is about 1 mg/mL to about 500 mg/mL of formulation. Igari *et al.* (US Patent 5,416,071) teach a pharmaceutical composition suitable of injection comprising erythropoietin (Examples 1-11) or other biological agents such as NGF (Example 12) and hyaluronic acid, where hyaluronic acid, a high molecular weight compound which is known to be biodegradable and pharmacologically injectable at the concentration of 0.01 to 3% (weight to volume). However, Igari *et al.* is silent on the microcapsule component such as a polymeric matrix used in the formulation. Since the two references either alone or in combined do not teach or suggest the injectable formulation comprising (a) an injection vehicle comprising hyaluronic acid dissolved in a physiological buffer at a concentration of about 0.01 to about 3% (w/v), and (b) a particle comprising a biologically active agent and a biocompatible polymeric matrix, where the concentration of the polymeric matrix is about 1 mg/mL

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to about 500 mg/mL of formulation. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

August 14, 2007